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10/586,348	10/13/2006	Alexandra M.C.R. Alves	0508-1167	2683
465 7590 06/07/2010 YOUNG & THOMPSON 209 Madison Street Suite 500 Alexandria, VA 22314				
			EXAMINER LEE, JAE W	
			ART UNIT 1656	PAPER NUMBER
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

DocketingDept@young-thompson.com

Office Action Summary

Application No.

10/586,348

Applicant(s)

ALVES ET AL.

Examiner

JAE W. LEE

Art Unit

1656

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 05 March 2010.
2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 40-62 is/are pending in the application.
4a) Of the above claim(s) 52-57 is/are withdrawn from consideration.
5) ☐ Claim(s) _____ is/are allowed.
6) ☒ Claim(s) 40-51 and 58-62 is/are rejected.
7) ☐ Claim(s) _____ is/are objected to.
8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/GS/US)
4) ☐ Interview Summary (PTO-413)
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____
Paper No(s)/Mail Date _____

DETAILED ACTION

Application status

In response to the previous Office action, a non-Final rejection (mailed on 11/05/2009), Applicants filed a response and amendment received on 03/05/2010. Said amendment canceled Claims 1-39, and added Claims 40-62. Thus, Claims 40-51 and 58-62 are at issue and present for examination.

Applicants' arguments filed on 03/05/2010, have been fully considered, and are deemed to be persuasive to overcome some of the rejections previously applied. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn.

The text of those sections of Title 35 U.S. Code not included in the instant action can be found in a prior Office action.

It is noted by the Examiner that Claims 52-57 are withdrawn from further consideration by the Examiner, 37 CFR 1.142(b) as being drawn to a non-elected invention in the previous Office actions, a non-Final rejection (mailed on 03/05/2010).

Objections to the Specification

The previous objection to the specification for failing to comply with sequence rules as set forth in 37 CFR 1.821(a)(1) and (a)(2) is withdrawn by virtue of Applicants' amendment.

Arrangement of the Specification

The previous objection of the specification is withdrawn by virtue of Applicants' amendment.

Claim Objections

The previous objection of Claims 21, 25 and 28-33 for the recitations of "-" or "***" is withdrawn by virtue of Applicants' amendment.

Claims 40-51, 59 and 60 are objected to because of the following informalities:

Claims 40-51, 59 and 60 are objected to for reciting strain names without italicizing such words, i.e., "Pycnopus cinnabarinus", "halocyphina villosa", etc.

Claim 42 is objected to for missing a space in the phrase, "proteinsor" in line 3.

Claim 43 is objected to for reciting "(a)" and "(b)" because "(a)" and "(b)" have been used in the claim 40 which claim 43 depends from. In order to improve form, the Examiner suggests replacing "(a)" and "(b)" with ---(I)--- and ---(II)---, respectively.

Claim 47 is objected to for reciting "recombinant laccase ... are prepared" in line 2-4 which has incorrect grammar (singular subject with the plural form of a verb). The Examiner suggests replacing the noted phrase with ---recombinant laccases ... are prepared---.

Claims 40 and 51 are objected to for reciting “j” in line 12 and line 9, respectively.
The Examiner suggests deleting the typographical mistake.

Appropriate correction is required.

Claim Rejections - 35 U.S.C. § 112

The following is a quotation of the second paragraph of 35 U.S.C. § 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

All of the previous rejection of Claims 21-33 under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention, are withdrawn because Applicants have canceled Claims 21-33.

Claims 40-51 and 58-62 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 40-51 and 58-62 recite the phrase “when the latter is inducible” which is unclear and indefinite. It is unclear with respect to what “the latter” is referring to. In the interest of advancing prosecution, the noted phrase is not given any patentable weight.

Claim Rejections - 35 U.S.C. § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

The previous rejection of Claims 21-31 under 35 U.S.C. § 102(a) as being anticipated by Alves et al. (Highly efficient production of laccase by the Basidiomycete *Pycnoporus cinnabarinus*, Applied and Environmental Microbiology, Vol. 70, No. 11, Nov. 2004, pp: 6379-6384, see IDS) as evidenced by Herpoel et al. (Selection of *Pycnoporus cinnabarinus* strains for laccase production, FEMS Microbiology Letters, 183, (2000), pp: 301-306, see IDS) is withdrawn because Applicants have perfected the foreign priority by providing an English translation of FRANCE 0400366 filed on 01/15/2004.

Claim Rejections - 35 U.S.C. § 103

The following is a quotation of 35 U.S.C. § 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The previous rejection of Claim 21-32 under 35 U.S.C. § 103(a) as being unpatentable over Lomascolo et al. (Overproduction of laccase by a monokaryotic strain of *Pycnoporus cinnabarinus*, Journal of Applied Microbiology, 94, pp: 618-624, 2003, see IDS) in view of Halaouli et al. (Characterization of a new tyrosinase from *Pycnoporus* species with high potential for food technological applications, Journal of

Applied Microbiology, published online in Nov. 2004, 98, pp: 332-343), KSR International Co. v. Teleflex Inc., 550 U.S.--, 82 USPQ2d 1385 (2007), and the evidentiary references of Herpoel et al. (Selection of *Pycnoporus cinnabarinus* strains for laccase production, FEMS Microbiology Letters, 183, (2000), pp: 301-306, see IDS) and Alves et al. (Highly efficient production of laccase by the Basidiomycete *Pycnoporus cinnabarinus*, Applied and Environmental Microbiology, Vol. 70, No. 11, Nov. 2004, pp: 6379-6384, see IDS), is withdrawn because Applicants have perfected the foreign priority by providing an English translation of FRANCE 0400366 filed on 01/15/2004.

Claims 40-46, 48, 49, 58 and 62 are rejected under 35 U.S.C. 103(a) as being obvious over Sigoillot et al. (Laccase production by a monokaryotic strain of *Pycnoporus cinnabarinus* derived from a dikaryotic strain, World Journal of Microbiology & Biotechnology, 15, 481-484, 1999, see IDS) in view of Record et al., "Expression of the *Pycnoporus cinnabarinus* laccase gene in *Aspergillus niger* and characterization of the recombinant enzyme", EUROPEAN JOURNAL OF BIOCHEMISTRY, vol. 269, no. 2, 2002, pp: 602-609, see IDS), Rigaut et al. (A generic protein purification method for protein complex characterization and proteome exploration, Nature Biotechnology, Vol. 17, 1999, pp: 1030-1032), KSR International Co. v. Teleflex Inc., 550 U.S.--, 82 USPQ2d 1385 (2007), and the evidentiary references of Herpoel et al. (Selection of *Pycnoporus cinnabarinus* strains for laccase production, FEMS Microbiology Letters, 183, (2000), pp: 301-306, see IDS).

The instant claims are drawn to a method for preparing a specific recombinant protein, said method being carried out by overexpression of a gene encoding for a specific recombinant protein in a monokaryotic strain of filamentous fungi of the species *Pycnoporus* of the basidiomycete group, comprising: (a) a stage of culturing the abovementioned monokaryotic strain of *Pycnoporus*, said strain being transformed using an expression vector containing a gene encoding for a specific recombinant protein, the expression of which is placed under the control of a promoter corresponding to an endogenous promoter of the abovementioned fungi, or of a exogenous promoter, said promoter being constitutive or inducible, (b) a stage of induction of the abovementioned promoter, and (c) recovering and purifying of the specific recombinant protein, produced in the culture medium. See above rejections under 112 2nd paragraph, and claims objections for the claim interpretation.

Sigoillot et al. teach a method comprising (I) culturing *Pycnoporus cinnabarinus* to over-express laccase by the use of monokaryotic strain, *Pycnoporus cinnabarinus* which is under control of an endogenous promoter, (II) inducing the laccase production by adding ferulic acid (has an aromatic ring), and (III) recovering and purifying the laccase (see page 481-2, under "Materials and Methods"). Furthermore, Sigoillot et al. teach that the advantage of monokaryotic strains is genetically more stable and produce a higher laccase activity than the dikaryotic parent strain under the same growth conditions (see page 483, left column). It is noted by the Examiner that laccase is an oxido-reductase belonging to the blue copper enzyme family, i.e., a metalloenzyme).

Sigoillot et al. do not teach the use of expression vector containing promoter and histidine tag to over-express said laccase.

Record et al. teach the recombinant expression of laccase from *Pycnoporus cinnabarinus* using expression vectors under control of the *A. nidulans* gpd promoter. Record et al. further teach a method of transforming a fungal host strain *A. niger* using said expression vectors, recombinantly expressing said laccase, and recovering and purifying said laccase (see under "EXPERIMENTAL PROCEDURES" on pages 603-605). It is noted by the Examiner that *A. nidulans* gpd promoter and *S. commune* gdp promoter are art-recognized equivalents as being a constitutive promoter.

Rigaut et al. teach the use of affinity tags, His-tag, for fast and reliable methods of recombinant protein purification (see Page 1030).

Therefore, it would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to practice a method comprising (I) culturing *Pycnoporus cinnabarinus* to over-express laccase by the use of monokaryotic strain, *Pycnoporus cinnabarinus* which is under control of an endogenous promoter, (II) inducing the laccase production by adding ferulic acid (has an aromatic ring), and (III) recovering and purifying the laccase as taught by Sigoillot et al. and use the expression vector comprising the laccase gene from *Pycnoporus cinnabarinus* under the control of a gpd promoter as taught by Record et al. because the use of monokaryotic *P. cinnabarinus* strain is advantageous for having genetic stability and high laccase activity as taught by Sigoillot et al. One of ordinary skill in the art would have been motivated to practice such methods because [i] placing said gene under the control of a promoter,

and deleting the corresponding endogenous gene would make optimization and control of the over-expression of said genes easier, and [ii] tagging the encoded proteins with an affinity tag, i.e., histidine tag, would make the subsequent purification of the encoded proteins easier. Furthermore, there is a high expectation of success for practicing such methods because [a] methods for obtaining monokaryotic strain of *Pycnoporus cinnabarinus* was routine in the prior art as evidenced by Herpoel et al. (Selection of *Pycnoporus cinnabarinus* strains for laccase production, FEMS Microbiology Letters, 183, (2000), pp: 301-306, see IDS), and [b] methods for over-expressing laccases via use of expression vectors comprising a promoter and an affinity tag was routine in the prior art as evidenced by Record et al. and Rigaut et al. While a single reference might not teach a specific embodiment of the claimed methods, the combination of references as noted above does disclose that the use of an expression vector comprising a promoter and an affinity tag for the expression of laccases in a monokaryotic strain of *Pycnoporus cinnabarinus* as being appropriate. As discussed in KSR International Co. v. Teleflex Inc., 550 U.S.--, 82 USPQ2d 1385 (2007), it is considered obvious to combine prior art elements known to be used in equivalent fields of endeavor together into a single combination. The references clearly show that the claimed methods were known to be used in equivalent fields of endeavor; thus, it is considered obvious to combine them together. For the reasons described above, the claimed methods are *prima facie* obvious over the combined teachings of the prior art.

Conclusion

Claims 40-51 and 58-62 are rejected for the reasons as stated above. It is noted by the Examiner that all of the objections and rejections stated herein are necessitated by Applicants' amendment to claims. Applicants must respond to the objections/rejections in this Office action to be fully responsive in prosecution.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jae W. Lee whose telephone number is 571-272-9949. The examiner can normally be reached on M-F between 9:00-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Manjunath Rao can be reached on 571-272-0939. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/JAE W LEE/
Examiner, Art Unit 1656

/SUZANNE M. NOAKES/
Primary Examiner, Art Unit 1656